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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/760,476 | 01/21/2004 | Steven Bernard | JHN-3659-79 | 9797 |

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| EXAMINER | |
|---|---|
| DEAK, LESLIE R | |

| ART UNIT | PAPER NUMBER |
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| 3761 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/760,476 | BERNARD ET AL. | |
| | Examiner | Art Unit | |
| | LESLIE R. DEAK | 3761 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2 and 4-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 November 2007* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 April 2008 has been entered.

### *Drawings*

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the pump and extracorporeal blood circuit as set forth in claims 1, 14, 19, 29, and 30 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 14, 19, 29, and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant claims a combination of a tube and an extracorporeal blood circuit with a pump. Applicant's specification does not set forth the circuit and the pump as contemplated portions of the invention, and there is no indication in the specification or the prosecution history that applicant's invention contemplated the combination of a tube with a circuit and pump. Accordingly, it is the position of the Examiner that Applicant did not, at the time of filing,

consider the invention to incorporate an extracorporeal circuit with a pump, making the claim limitations new matter.

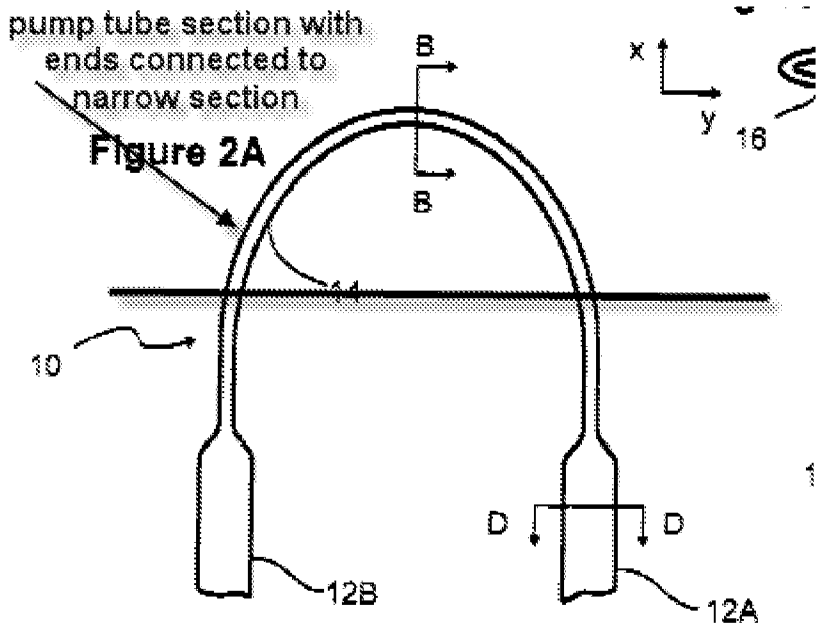
### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 2, and 4-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,494,693 to Sunden in view of US 4,954,055 to Raible et al.

In the specification and figures, Sunden discloses the device substantially as claimed by applicant. With regard to claims 1-2, 15, 19, Sunden discloses a pump tube 10 comprising a first end 12A with a first inside diameter (see FIG 2D), a narrow center section of the tube 14 with a minor diameter (see 16 in FIG 2B) narrower than the first diameter. The tube ends with a second tube end with a diameter and cross-sectional area at least as large as the first diameter (see FIG 2A). The narrower diameter in the center helps to prevent backflow in situations where a backpressure may develop, such as in the case of a clogged filter (see column 7, lines 5-10). Sunden further illustrates a tapered tube transition section between the areas of different diameters (see FIG 2A). Sunden discloses that the tube is used to pass sensitive biological materials, such as blood (indicating an extracorporeal circuit) through pump 30 (see column 1, lines 23-25).




Sunden fails to disclose that the center pump section of the tube comprises an area with a diameter greater than that of the narrowed section. Raible discloses a pump tube with narrow end sections 16, 18, and a center pump section 20 of increased diameter, with tapered sections in between, wherein the area of increased diameter provides for less turbulent pumping of blood through the pumping section of the tube (see column 1, lines 20-31, column 2, lines 13-24).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a small area of increased diameter as disclosed by Raible to the pump tube disclosed by Sunden in order to prevent backflow as taught by Sunden, while decreasing hemolysis, as taught by Raible.

With regard to applicant's recitation of the length of the increased and decreased diameter sections as a percentage of the total tube length, discrete lengths of the sections, and relative diameters (see claims 1, 4, 8, 14, 15, 19, 31), both Sunden and

Raible disclose that the length, shape, and overall proportions of tube sections are variable according to the shape and size of the pump used (see Sunden, column 13, line 57 to column 14 line 14; Raible column 3, lines 38-43). These teachings indicate that the length of the tubing and the length of the sections of various diameter are result-effective variables that depend on the configuration of the pump being used with the tubing. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimal or workable ranges involves only routine skill in the art. See MPEP 2144.05 (II)(A) It has also been held that where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device. See MPEP 2144.04(I)(A). In the instant case, it is the position of the examiner that since Sunden and Raible disclose that the dimensions of the tube lengths are variable, and there is no evidence that the sizes claimed by applicant perform differently than the device suggested in the prior art, applicant's claimed proportions are an obvious variation of the prior art.

With regard to claims 2 and 7, Raible illustrates that the wider middle section engages with a pump, illustrating that the narrower sections are not engaged with a pump (see FIG 1).

With regard to claims 5, 16, 17, 21, and 22, Sunden illustrates that all sections of the pump tube comprise substantially the same wall thickness (see Sunden FIGS 2B,

2C, 2D), and Raible indicates that the tube wall 26 remains "substantially constant" throughout the length of the tube (see Raible column 3, lines 16-19).

With regard to claims 6 and 20, Sunden discloses that the inner diameter of the fluid passageway of the reduced diameter pump section may range from 0.1 to 4mm, meeting applicant's claim drawn to a diameter of 0.06in (see column 12, lines 55-67). Sunden further discloses that the outer diameter of the normal diameter, non pump portion of the tube will range from 12-16mm, with the outer diameter of the pump section will range from 2-18mm (see column 13, lines 1-10). Sunden illustrates the outer diameter of the pumping section to be smaller than that of the larger section, meeting the limitations of applicant's claims (see FIGS 2A-2D).

With regard to claims 9-12, 18, 23, 24, and 26, Sunden discloses that first and second ends of the single-lumen tube are attachable to a connector (not shown, see column 7, lines 19-25). Sunden further illustrates that the transition from the wide section to the narrow section is a smooth transition, teaching that abrupt changes in the direction of the tube (such as sharp turns or edges) should be avoided (see FIG 2A, column 7, lines 40-48).

With regard to claims 13 and 25, Sunden discloses that the tube may be manufactured from PTFE, which is a biocompatible polymer (see column 12, lines 8-25).

With regard to claims 27 and 28, Sunden discloses that the tube is used to pass sensitive biological materials therethrough, which may include blood (see column 1, lines 23-25).

With regard to claims 29-30, the combined references provide a wide pump tube section (as disclosed by Raible) with surrounding narrow sections (as disclosed by Sunden) wherein the narrow sections are distinct from the pump tube section, meeting the limitations of the claims. Sunden fails to disclose the proportional length of the tubing sections. Sunden disclosed that the length, shape, and overall proportions of tube sections are variable according to the shape and size of the pump used (see Sunden, column 13, line 57 to column 14 line 14). These teachings indicate that the length of the tubing and the length of the sections of various diameter are result-effective variables that depend on the configuration of the pump being used with the tubing. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimal or workable ranges involves only routine skill in the art. See MPEP 2144.05 (II)(A) It has also been held that where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device. See MPEP 2144.04(I)(A). In the instant case, it is the position of the examiner that since Sunden discloses that the dimensions of the tube lengths are variable, and there is no evidence that the sizes claimed by applicant perform differently, providing unexpected results, than the device suggested in the prior art, applicant's claimed proportions are an obvious variation of the prior art.

***Response to Arguments***

7. Applicant's amendment and arguments filed 30 April 2008 have been entered and fully considered.

8. Applicant argues that claims 29 and 30 are not rendered obvious by Sunden since the narrow tube sections are claimed as distinct from the pump tube section. The Examiner agrees, and has amended the rejection to address this new limitation.

9. Applicant argues that the proportions of the tubing lengths should be given patentable weight. It is the position of the Examiner that absent any showing of *objective* evidence that the instantly claimed proportions provide an unexpected result over the suggestions of the prior art, the length of each section of tubing is variable, via routine experimentation, to one having ordinary skill in the art.

10. Applicant argues that Raible "teaches away" from the claimed invention. The Examiner respectfully disagrees. While Raible does not disclose the specific details of applicant's invention, such a silence does not constitute a "teaching away" from the combination. Sunden teaches a pump tube with a small diameter sections that prevent backflow in a high pressure device. Raible recognizes that while narrow tube sections reduce the extracorporeal blood volume, such narrow tubes increase hemolysis, especially in pump tube sections, and teaches a narrow tubing line with a pump tube section of increased diameter. These teachings suggest to one of ordinary skill in the art the desirability of a tube with variable diameter sections in order to prevent both backflow and blood damage. The references teach different advantages to their particular configurations, but do not "teach away" from one another.

***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
13 June 2008